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Section 5
510(k) Summary of Safety and Effectiveness Information

Hickman® TriFusion™ Catheters

5.1 Submitter Information:

Submitter Name:	Bard Access Systems, Inc. (BAS) (Wholly owned Subsidiary of C.R. Bard, Inc.)
Address:	5425 W. Amelia Earhart Drive Salt Lake City, UT 84116
Telephone Number:	(801) 595-0700, Ext. 7136
Fax Number:	(801) 595-5425
Contact Person:	Lynn M. Kirchoff
Date of Preparation:	August 17, 2004

5.2 Device Name:

Device Name:	Hickman® **TriFusion™** Catheter
Trade Name:	**TriFusion™**
Common/Usual Name:	Long-Term Intravascular Catheter
Classification Name:	80 LJS – Long-Term Intravascular Catheter 21 CFR 880.5970 – Class II Implanted Blood Access Device
Classification Panel:	General Hospital

5.3 Predicate Device:

Device Name:	**Hickman®** Long-Term Central Venous Catheter
Trade Name:	**Hickman®**
Common/Usual Name:	Long-Term Intravascular Catheter
Classification Name:	80 LJS – Long-Term Intravascular Catheter 21 CFR 880.5970 – Class II Implanted Blood Access Device
Classification Panel:	General Hospital
Premarket Notification:	K830233, cleared for marketing on February 28, 1983

5.4 Device Description:

The device description of the subject Hickman **TriFusion™** Catheter is as follows:

- The Hickman **TriFusion™** Catheters are open-ended triple lumen radiopaque polyurethane catheters.
- The Hickman **TriFusion™** Catheters are 12 Fr triple lumen with up to 27 cm insertion length.
- The Hickman **TiFusion™** Catheters have three equal sized lumens with the distal lumen extending beyond the proximal lumens.
- The proximal end of the **TriFusion™** Catheter consists of three luer connectors, occlusion clamps, and priming volume ID tags.
- Catheters are provided sterile in two kit configurations, an Intermediate Tray and a Microintroducer (MI) Tray.

5.5 **Intended Use:**

The Hickman® TriFusion™ Triple Lumen Long-Term Central Venous Catheter is indicated for use in attaining short term or long term vascular access for intravenous infusion therapy and blood sampling via the internal jugular vein, external jugular vein, and subclavian vein.

All Hickman® TriFusion™ catheters are designed for apheresis, and the administration of I.V. fluids, blood products, drugs, and parenteral nutrition solutions, as well as blood withdrawal. The Hickman® TriFusion™ catheter incorporates three large, equal size lumens appropriate for apheresis procedures.

This is the same intended use as the currently marketed 12.5 Fr T/L Hickman catheter covered by K830233, concurrence date 02/28/1983.

5.6 **Technological Characteristics Summary:**

510(k) Substantial Equivalence Decision Tree:

New device is compared to Marked Device?

Yes.

Does the new device have the same indication statement as the predicate?

Yes, with minor modifications to the indication verbiage.

Does the new device have the same technological characteristics, e.g. design, material, etc.?

Not in all regards. The **TriFusion™** Catheters have some minor differences from the predicate T/L Hickman Catheters. However, the basic fundamental scientific technology of the catheter has not changed.

Could the new characteristics affect safety or effectiveness?

Yes. The new characteristics could affect the safety or effectiveness of the device.

Do the new characteristics raise new types of safety and effectiveness questions?

No. There are no new types of safety and effectiveness questions.

Do accepted scientific methods exist for assessing effects of the new characteristics?

Yes. Reliance was placed on recognized standards to evaluate the device's performance.

- *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, dated 3/16/95*
- *ISO 10555-1:1997, Sterile, single-use intravascular catheters, Part 1. General requirements*
- *ISO 10555-3:1997, Sterile, single-use intravascular catheters, Part 3. Central venous catheters*
- *ISO 594-1:1986, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment-Part 1: General Requirements*
- *ISO594-2:1986, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment-Part 2:Luer Fittings*

Are performance data available to assess effects of new characteristics?

Yes. Verification testing was preformed according to the referenced standards, as well as in accordance with in-house protocols. The test results met the requirements and were compared to the predicate devices.

Do performance date demonstrate equivalence?

Yes. Performance data demonstrate that the **TriFusion™** Catheters are substantially equivalent to the predicate 12.5 Fr T/L Hickman® Catheters.

5.7 Nonclinical Performance Testing

Testing was performed per FDA's *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, dated 3/16/95*:

Biocompatibility

Guidance Testing Performed

1) Dimensions
2) Flow rate
3) Tensile, Elongation and Stiffness (modulus) of catheter body
4) Tensile strength of catheter body to hub [connector] attachment (Assembly)
5) Catheter tip (distal) attachment strength
6) Leakage at hub
7) Catheter burst pressure (positive internal pressure)
8) Catheter collapse (negative internal pressure)
9) Catheter flexural fatigue tolerance (Body & Tip)

In-House Protocols

Additional Tests to Establish Safety & Effectiveness:

10) Hemolysis
11) Priming volume
12) PET cuff bond tensile strength
13) Radiopacity
14) Tunneler security test
15) Recirculation

5.8 Conclusion:

The Hickman **TriFusion™** catheter is substantially equivalent to the legally marketed predicate device, the 12.5 Fr T/L Hickman Long-Term Catheter, covered by K830233, concurrence date 02/28/1983.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 1 2004

Ms. Lynn M. Kirchoff
Regulatory Affairs Specialist
Bard Access Systems, Incorporated
5425 West Amelia Earhart Drive
Salt Lake City, Utah 84116

Re: K041088
Trade/Device Name: Hickman® TriFusion™ Catheter
Regulation Number: 880.5970
Regulation Name: Percutaneous Implanted Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: August 17, 2004
Received: August 18, 2004

Dear Ms. Kirchoff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

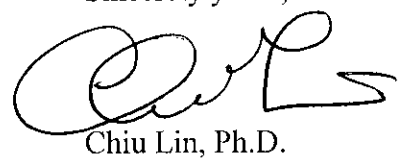
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ___K041088_____

Device Name: _Hickman® TriFusion™ Catheter_____

Indications for Use:

The Hickman® TriFusion™ Triple Lumen Long-Term Central Venous Catheter is indicated for use in attaining short term or long term vascular access for intravenous infusion therapy and blood sampling via the internal jugular vein, external jugular vein, and subclavian vein. All Hickman® TriFusion™ catheters are designed for apheresis, and the administration of I.V. fluids, blood products, drugs, and parenteral nutrition solutions, as well as blood withdrawal. The Hickman® TriFusion™ catheter incorporates three large, equal size lumens appropriate for apheresis procedures.

Prescription Use \ ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K041088